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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,821	06/09/2002	Robert Short	H0664/7002	2143

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,821	SHORT ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12 and 15-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-12 and 15-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 3/29/06 amended claims 1, 5-7 and 16-18, and canceled claims 4, 13 and 14.

Claims examined on the merits are 1-3, 5-12 and 15-32, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-12 and 15-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Bridging lines 1 and 2 of claim 1, "acute and/or chronic cutaneous wounds" is not found in the specification. The page and line should be pointed out where this recitation occurs in the specification, or is believed to be supported by the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-12 and 15-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Bridging lines 1 and 2 of claim 1, "acute and/or chronic cutaneous wounds" encompasses a cutaneous wound being both acute and chronic at the same time. It is uncertain how these two wound conditions can exist together for the same wound.

In line 5, claim 1 is unclear as to whether "a wound bed" is the "acute and/or chronic cutaneous wounds" bridging lines 1 and 2, or is some other wound.

Claim 28 is confusing by requiring treatment of cutaneous wounds in line 1 and ultimately depending on claim 1 that requires the therapeutic vehicle to be adapted for application to "acute and/or chronic cutaneous wounds". Are the cutaneous wounds in claim 28 the acute and/or chronic cutaneous wounds in claim 1, or some other wound?

Claim Rejections - 35 USC § 103

Claims 1-3, 6-12 and 15-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daw et al (C1 on form 1449) or France et al

(C2 on form 1449) in view of Mayes et al (6,150,459) and McAuslan (WO 87/05038) for reasons in the previous office action of 11/25/05, and for reasons herein.

The claims are drawn to a therapeutic vehicle adapted for application to acute and/or chronic cutaneous wounds comprising a cell culture surface having a carboxylic acid functionality of at least 5% to which keratinocytes can attach and detach to transfer to a wound bed. The cell culture surface can be prepared by plasma polymerization of acrylic acid or a copolymer of acrylic acid and 1,7-octadiene to coat a substrate. The surface can have a carboxylic acid functionality of 5-20% or greater than 20%. Also claimed is a method of preparing a cell culture surface of the therapeutic vehicle, and a method for treatment of cutaneous wounds using the therapeutic vehicle.

Daw et al and France et al disclose plasma polymerization of acrylic acid or plasma co-polymerization of acrylic acid and 1,7-octadiene on a substrate such as foil, or tissue culture wells or dishes to produce a surface containing acid functionality that binds cells and can be used for cell culture. The percent acid functionality can be in the range of 5-20% or greater than 20%. For example, see Daw et al (page 1718, under "Experimental procedure"; paragraph bridging the columns and Figure 3 on page 1720; Figures 5 and 6 on page 1722; under "Discussion" on page 1723; and under "Conclusions" on page 1724). Also see France et al (paragraph bridging pages 37 and 38; under "Cell attachment assay" and under

"Characterisation of PCPs" and Table 1 on page 38; under "Discussion" on page 41; and under "conclusions" on page 42).

Mayes et al disclose coating the surface of a material with a copolymer, seeding the coating with cells, and implanting (col 16, lines 58-65) for tissue engineering (col 16, line 53). Also disclosed is wound-heating application (col 16, line 14).

McAuslan discloses forming an implant by applying to a substrate a hydrogel layer to which cells bind (page 5, lines 15-29).

It would have been obvious to apply the cell-binding polymer or copolymer of Daw et al or France et al to a substrate for implanting as suggested by Mayes et al and McAuslan applying a cell-binding polymer to a substrate to provide an implant, which can be seeded with cells. The resulting implantable substrate containing the cell binding polymer or copolymer of Daw et al or France et al is a therapeutic vehicle as presently claimed, and is inherently capable of being applied to acute and/or chronic cutaneous wounds and permitting keratinocytes to attach and detach to transfer to a wound bed. The cell binding surface resulting from plasma polymerization as disclosed by Daw et al or France et al is the same as the cell culture surface of the therapeutic vehicle presently claimed, and contains an acid functionality as presently claimed.

Response to Arguments

Applicant's arguments filed 3/29/06 have been fully considered but they are not persuasive.

Applicants urge that Daw et al and France et al do not disclose attachment, growth and detachment of keratinocytes. However, the present claims do not require attaching, growing and detaching keratinocytes. The claims instead require that keratinocytes "can" attach and detach to transfer to a wound bed. Keratinocytes will inherently be capable of attaching, growing and detaching from an implantable substrate containing the cell binding polymer or copolymer of Daw et al or France et al. Furthermore, Daw et al and France et al bind to the cell binding surface osteoblasts and keratinocytes, respectively, which would have suggested that keratinocytes can attach to an implantable substrate resulting from applying the cell-binding polymer or copolymer of Daw et al or France et al to a substrate.

Claim Rejections - 35 USC § 103

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-3, 5-12 and 15-32 above, and further in view of Yanagihara et al (4,693,799).

The claim requires propionic acid as the acid subjected to plasma polymerization to produce the cell culture surface.

Yanagihara et al disclose (col 6, lines 44-45 and line 58) producing a plasma polymerized film enriched in hydroxyl or carboxyl groups by plasma polymerizing an acid such as propionic acid.

When producing copolymer of Daw et al or France et al on an implantable substrate as set forth above, it would have been obvious to use propionic acid in place of the acrylic acid of Daw et al or France et al since Yanagihara et al suggest that propionic acid will

provide the function of acrylic acid by disclosing plasma polymerization of propionic acid to produce a film containing carboxyl groups.

Response to Arguments

Applicants urge that Yanagihara et al do not supply elements stated to be missing in the rejection above. However, for reasons set forth above, elements are not missing that will make the claimed invention unobvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff

whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
6/27/06